

EXHIBIT 320-1

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID
NATIONAL COVERAGE DECISION FOR LUNG VOLUME REDUCTION SURGERY
(REDUCTION PNEUMOPLASTY)**

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CENTERS FOR MEDICARE AND MEDICAID
NATIONAL COVERAGE DECISION (NCD) FOR LUNG VOLUME REDUCTION SURGERY
(REDUCTION PNEUMOPLASTY) (240.1)**

Effective Date of this Version

11/17/2005

A. General

Lung volume reduction surgery (LVRS) or reduction pneumoplasty, also referred to as lung shaving or lung contouring, is performed on patients with severe emphysema in order to allow the remaining compressed lung to expand, and thus, improve respiratory function. Medicare-covered LVRS approaches are limited to bilateral excision of a damaged lung with stapling performed via median sternotomy or video-assisted thoracoscopic surgery.

Indications and Limitations of Coverage

B. Nationally Covered Indications

Effective for services performed on or after January 1, 2004 Medicare will only consider LVRS reasonable and necessary when all of the following requirements are met (note varying dates for facility criteria in section 3. below):

1. The patient satisfies all the criteria outlined below:

Assessment	Criteria
History and physical examination	Consistent with emphysema
	BMI, $\leq 31.1 \text{ kg/m}^2$ (men) or $\leq 32.3 \text{ kg/m}^2$ (women)
	Stable with $\leq 20 \text{ mg}$ prednisone (or equivalent) qd
Radiographic	High Resolution Computer Tomography (HRCT) scan evidence of bilateral emphysema
Pulmonary function (pre-rehabilitation)	Forced expiratory volume in one second (FEV_1) $\leq 45\%$ predicted $\geq 15\%$ predicted if age ≥ 70 years)
	Total lung capacity (TLC) $\geq 100\%$ predicted post-bronchodilator
	Residual volume (RV) $\geq 150\%$ predicted post-bronchodilator
Arterial blood gas level (pre-rehabilitation)	PCO_2 , $\leq 60 \text{ mm Hg}$ (PCO_2 , $\leq 55 \text{ mm Hg}$ if 1-mile above sea level)
	PO_2 , $\geq 45 \text{ mm Hg}$ on room air (PO_2 , $\geq 30 \text{ mm Hg}$ if 1-mile above sea level)
Cardiac assessment	Approval for surgery by cardiologist if any of the following are present: Unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF $<45\%$; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest)

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Surgical assessment	Approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation
Exercise	Post-rehabilitation 6-min walk of ≥ 140 m; able to complete 3 min unloaded pedaling in exercise tolerance test (pre- and post-rehabilitation)
Consent	Signed consents for screening and rehabilitation
Smoking	Plasma cotinine level ≤ 13.7 ng/mL (or arterial carboxyhemoglobin $\leq 2.5\%$ if using nicotine products)
	Nonsmoking for 4 months prior to initial interview and throughout evaluation for surgery
Preoperative diagnostic and therapeutic program adherence	Must complete assessment for and program of preoperative services in preparation for surgery

2. In addition, the patient must have:

- Severe upper lobe predominant emphysema (as defined by radiologist assessment of upper lobe predominance on CT scan), or
- Severe non-upper lobe emphysema with low exercise capacity.

Patients with low exercise capacity are those whose maximal exercise capacity is at or below 25 watts for women and 40 watts (w) for men after completion of the preoperative therapeutic program in preparation for LVRS. Exercise capacity is measured by incremental, maximal, symptom-limited exercise with a cycle ergometer utilizing 5 or 10 watt/minute ramp on 30% oxygen after 3 minutes of unloaded pedaling.

3. Effective for services performed on or after November 17, 2005, CMS determines that LVRS is reasonable and necessary when performed at facilities that are:

(1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program (program standards and requirements as printed in the Joint Commission's October 25, 2004, Disease Specific Care Certification Program packet); or (2) approved as Medicare lung or heart-lung transplantation hospitals.

In addition, LVRS performed between January 1, 2004, and May 17, 2007, is reasonable and necessary when performed at facilities that: (1) were approved by the National Heart Lung and Blood Institute to participate in the National Emphysema Treatment Trial (NETT); or (2) are approved as Medicare lung or heart-lung transplantation hospitals.

A list of approved facilities and their approval dates will be listed and maintained on the CMS Web site at http://www.cms.hhs.gov/MedicareApprovedFacilitie/04_lvrs.asp#TopOfPage.

The surgery must be preceded and followed by a program of diagnostic and therapeutic services consistent with those provided in the NETT and designed to maximize the patient's potential to successfully undergo and recover from surgery. The program must include a 6- to 10-week series of at least 16, and no more than 20, preoperative sessions, each lasting a minimum of 2 hours. It must also include at least 6, and no more than 10, postoperative sessions, each lasting a minimum of 2 hours, within 8 to 9 weeks of the LVRS. This program must be consistent with the care plan developed by the treating physician following performance of a comprehensive evaluation of the patient's medical, psychosocial

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and nutritional needs, be consistent with the preoperative and postoperative services provided in the NETT, and arranged, monitored, and performed under the coordination of the facility where the surgery takes place.

C. Nationally Non-covered Indications

1. LVRS is not covered in any of the following clinical circumstances:

- a. Patient characteristics carry a high risk for perioperative morbidity and/or mortality;
- b. The disease is unsuitable for LVRS;
- c. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery;
- d. The patient presents with FEV₁ <20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of <20% of predicted value (high-risk group identified October 2001 by the NETT); or
- e. The patient satisfies the criteria outlined above in section B(1), and has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 w for women and 40 w for men (under the measurement conditions for cycle ergometry specified above).

2. All other indications for LVRS not otherwise specified remain noncovered.